REMARKS

Reconsideration and withdrawal of the objections to and rejections of the application and/or holding rejections in abeyance until agreement otherwise on allowable subject matter, are respectfully requested, in view of the amendments and remarks and enclosures herewith and matters discussed with Examiner Badio and Practice Specialist Reynolds during the May 13, 2004 personal interview among Examiner Badio, Practice Specialist Reynolds, Drs. David Alcock and John Normanton, Prof. Barry Potter, and the undersigned, for which Examiner Badio and Practice Specialist Reynolds are thanked for the courtesies extended.

I. FORMAL MATTERS AND STATUS OF THE CLAIMS

Claims 8-16 have been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. No new matter is added.

It is submitted that the claims as previously presented were in full compliance with the requirements for patentability. The amendments to the claims and the remarks herein and the enclosures herewith are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks and enclosures herewith are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Applicants respectfully assert that the present Amendment does not change the scope of the claims, nor does the amendment create estoppel.

II. CLAIM OBJECTIONS AND REJRECTIONS BASED ON FORMALITIES ARE OVERCOME

Claims 12-16 and 19 were objected to under 37 C.F.R. 1.75(c) as allegedly being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim.

Claim 8 was rejected under 35 U.S.C. 101 as allegedly claiming the same invention as that of claim 2 of prior U.S. Patent No. 6,187,766.

Reconsideration and withdrawal of this objections and rejections are respectfully requested as the claims are amended to address the formal objections and rejections, without change of scope, and without giving rise to any estoppel.

III. DOUBLE PATENTING REJECTIONS TO BE HELD IN ABEYANCE

Claims 6-11, 17, 18 and 20 were rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 1-12 of U.S. Patent No. 5,616,574.

Claims 6-11, 17, 18 and 20 were rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 1-3 of U.S. Patent No. 6,187,766.

Claims 6-11, 17, 18 and 20 were rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 1-19 of U.S. Patent No. 6,642,397.

Claims 6, 7, 9-11, 17, 18 and 20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 1-9 and 12-20 of copending Application No. 09/755,429.

Claims 6-11, 17, 18 and 20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 2-5 of copending Application No. 09/794,853.

Claims 6-11, 17, 18 and 20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 1-20 and 28-30 of copending Application No. 10/013,798.

Claims 6-11, 17, 18 and 20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 1-6 and 9-11 of copending Application No. 10/165,599.

Claims 6-11, 17, 18 and 20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 1-36 and 39-42 of copending Application No. 10/367,622.

Claims 6-11, 17, 18 and 20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over claims 1-13 and 19 of copending Application No. 09/572,237.

It is respectfully requested that the double patenting rejections be held in abeyance: when there is agreement as to allowable subject matter, Applicants can file a Terminal Disclaimer as to issued US Patents, if such is warranted in view of the nature of the claims upon which there is agreement as to allowability, or to expedite prosecution. And, the Examiner can withdraw the

"provisional" double patenting rejections as to other pending applications (making non-provisional double patenting rejections in the other pending applications, if such is warranted in view of the nature of the claims in those other pending applications and the claims upon which there is agreement as to allowability).

IV. THE ART REJECTION IS OVERCOME

Claims 6-11, 17, 18 and 20 were rejected under 35 U.S.C. 103(a) allegedly as being unpatentable over The Registry Handbook (1984 Supplement) in view of Schwarz et al. (DD 114806 and Hirsch (US Patent No. 4,075,351).

This rejection was among matters discussed with Examiner Badio and Practice Specialist Reynolds during the May 13, 2004 personal interview among Examiner Badio, Practice Specialist Reynolds, Drs. David Alcock and John Normanton, Prof. Barry Potter, and the undersigned, for which Examiner Badio and Practice Specialist Reynolds are thanked for the courtesies extended.

During the interview, the Declaration of Prof. Barry V.L. Potter, submitted herewith, was presented.

Prof. Potter is one of the named inventors on the above-captioned application ("the present application"). He is familiar with the text and prosecution of the present application, including the November 14, 2003 Office Action. Moreover, he is an author and inventor on articles and patents in the field to which the present invention pertains, and as such, is considered an expert in the field to which the present application pertains. He is also the Professor Barry V.L. Potter who made a November 23, 2002 Declaration in U.S. application Serial No. 09/794,853, filed February 27, 2001, a copy of which is attached to his Declaration in this application for completeness of the record. He is fluent in both the spoken and written forms of German.

A copy of Prof. Potter's *Curriculum vitae* and a listing of his publications is also submitted herewith.

Accordingly Prof. Potter is qualified to speak and render opinions about the present application and its prosecution.

Prof. Potter is advised and therefore believes that Claims 6-11, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) allegedly as being unpatentable over The Registry Handbook (1984 Supplement) in view of Schwarz et al. (DD 114806) and Hirsch (US Patent No. 4,075,351),

which he has read and with which he is familiar; and, his Declaration is directly responsive to that rejection.

Prof. Potter observes that The Registry Handbook merely provides the compound name, "19-norpregna-1,3,5(10)-triene-20-yne-3,17-diol, 3-sulfamate".

Prof. Potter states that from the mere naming of a compound, such as in The Registry Handbook, or a mere drawing of a compound, as in incorrect Abstract of DD 207447 (cited in USSN 09/794,853 by the same Examiner as in the present application), the skilled artisan is NOT provided with an enabling disclosure of how to make and use the compound.

Prof. Potter further states that prior to the effective filing date of the present application (August 29, 1991), there was no teaching or suggestion in the art, of which he is aware, of reacting a steroid, such as oestrone, 17 Beta-oestradiol, 17alpha-ethinyl-17Beta-oestradiol, 17alpha-oestradiol or oestriol, with unsubstituted sulfamoylchloride, or a polycyclic alcohol having at least four rings with at least two of those rings being fused with unsubstituted sulfamoylchloride.

Prof. Potter states that Schwartz employed a sterol and a substituted sulfamoylchloride.

In Prof. Potter's expert opinion, based upon his education, training, and experience, including personal experience working with Prof. Schwarz, the teachings in Schwarz cannot be applied to arrive at the compound of The Registry Handbook; and, more generally, cannot be applied to synthesize unsubstituted steroid sulphamates or unsubstituted polycyclic sulphamates having at least four rings with at least two of those rings being fused.

Prof. Potter notes that there is no teaching or suggestion in Schwarz of synthesizing unsubstituted steroid sulphamates or unsubstituted polycyclic sulphamates having at least four rings with at least two of those rings being fused by reacting a steroid, such as oestrone, 17 Beta-oestradiol, 17alpha-ethinyl-17Beta-oestradiol, 17alpha-oestradiol or oestriol, with unsubstituted sulfamoylchloride, or a reacting a polycyclic alcohol having at least four rings with at least two of those rings being fused with unsubstituted sulfamoylchloride.

Further bases for his opinion include that the unsubstituted sulphamate steroid esters are more polar than the N-alkyl amino sulphamates. And in the two-phase system of phase-transfer catalyzed acylation taught by Schwarz, in his view, the unsubstituted sulphamate steroid ester would be significantly transported to the aqueous phase and rapidly degraded.

Prof. Potter declares that unsubstituted sulphamate esters are more unstable than their N,N-alkyl counterparts.

Prof Potter states: "Simply, if one attempted to apply the Schwarz teachings to prepare unsubstituted steroid sulphamates or unsubstituted polycyclic sulphamates having at least four rings with at least two of those rings being fused, there would be a transport of any unsubstituted sulphamate to the aqueous phase in Schwarz and degradation."

Thus, Schwarz, in his opinion, cannot be applied to the preparation of unsubstituted steroid sulphamates or unsubstituted polycyclic sulphamates having at least four rings with at least two of those rings being fused.

Moreover, Prof. Potter's personal experience and interactions with Prof. Schwarz confirmed that the teachings in Schwarz, in fact, could not be applied to unsubstituted sulphamates.

For instance, Prof. Potter's recollection is that Prof. Schwarz admitted that his group abandoned the field, but only re-entered it after Prof. Potter's group's J. Med. Chem. 1994 publication Howarth et al., 1994 J. Med. Chem. 37:219-221, that has information as in the UK priority application of August 29, 1991 in the lineage of the instant application (which Prof. Schwarz' employer licensed).

This was further discussed during the interview with a few additional observations: The licensing of the instant application is a secondary indicia of patentability: commercial success.

Furthermore, it was noted that Prof. Schwarz was likely the world leader in the area of the instant application at its effective filing date, yet his group did not achieve the synthesis of the compound of The Registry Handbook. Instead, there was a license. Clearly Schwarz and his employer recognized the novelty and nonobviousness of the instant invention.

Moreover, the Schwarz document cited was filed in 1974 and published in 1975. The present application was filed about 17 years after the filing date of Schwarz, and the Howarth article was published about 20 years after the filing date of Schwarz. In the period of about 20 years after the filing and publication of Schwarz, no one reported the synthesis of the compound of The Registry Handbook, further showing that it could not be merely synthesized, e.g., by the methods of Schwarz and/or Hirsch, as asserted in the Office Action, i.e., the long period of time in the field from the publication and filing of Schwarz to the filing and publication of the instant application and of the technology in the instant application, with no one reporting the synthesis

of the compound of The Registry Handbook, demonstrates that it could not be merely synthesized, e.g., by the methods of Schwarz and/or Hirsch, as asserted in the Office Action. Indeed, during the interview it was discussed that synthesis of compounds of the instant invention and the compound of The Registry Handbook are not trivial exercises, and that syntheses can be unpredictable.

Accordingly, Schwarz, either individually or in combination with Hirsch (*see* discussion *infra*), cannot supply the deficiencies of the mere compound name in The Registry Handbook.

In Prof. Potter's expert opinion, based upon his education, training, and experience, the skilled artisan would not turn to Hirsch to synthesize unsubstituted steroid sulphamates or unsubstituted polycyclic sulphamates having at least four rings with at least two of those rings being fused.

Initially, Prof. Potter notes that The Registry Handbook, as mentioned above, merely provides the compound name, "19-norpregna-1,3,5(10)-triene-20-yne-3,17-diol, 3-sulfamate."

According to Prof. Potter, starting from this naked disclosure, the skilled artisan, in his view, would NOT turn to Hirsch, which has nothing to do with steroids; but rather, would turn to Schwarz, which involves steroids, but which cannot be employed to synthesize the compound of the bare disclosure of The Registry Handbook, as discussed herein.

More generally, Prof. Potter observes that there is no teaching or suggestion in Hirsch of synthesizing unsubstituted steroid sulphamates or unsubstituted polycyclic sulphamates having at least four rings with at least two of those rings being fused by reacting a steroid, such as oestrone, 17 Beta-oestradiol, 17alpha-ethinyl-17Beta-oestradiol, 17alpha-oestradiol or oestriol, with unsubstituted sulfamoylchloride, or a reacting a polycyclic alcohol having at least four rings with at least two of those rings being fused with unsubstituted sulfamoylchloride.

And, if one attempted to apply reaction conditions of Hirsch, in Prof. Potter's view, failure would also be met; for instance, in his view, a steroid would not be soluble in the solvent systems of Hirsch.

As to Hirsch, during the interview it was also discussed that Hirsch has an effective filing date of 1974 and issued in 1978, such that there is more than 13 years from Hirsch's issue date to the effective filing date of the present application, about 17 years from Hirsch's effective filing date to the effective filing date of the present application, and about 20 years from the filing date of Hirsch and the publication of the technology of the instant application.

That is, there was a long period between Hirsch and the instant invention; and, throughout that long period, no one reported the synthesis of the compound of The Registry Handbook, demonstrating that it could not be merely synthesized, e.g., by the methods of Schwarz and/or Hirsch, as asserted in the Office Action. Even further still, it was noted that Prof. Schwarz and his group and his employer clearly followed the technology in the field, e.g., as evinced by being in contact with and working with Prof. Potter after the publication of the technology of the instant application; and, that Prof. Schwarz, the world leader in the field at the effective filing date of the instant application did not look to Hirsch. Clearly, the skilled artisan would not look to Hirsch to attempt to synthesize the compound of The Registry Handbook; and, if he did, as observed by Prof. Potter, the skilled artisan would have met with failure.

And again, it is noted that during the interview it was discussed that synthesis of compounds of the instant invention and the compound of The Registry Handbook are not trivial exercises, and that syntheses can be unpredictable.

It is respectfully submitted that in view of the matters discussed during the interview and presented in the declaration, and the undisputed facts of the long gaps in time between (i) the filing and publication or issue dates of Schwarz and Hirsch and (ii) the effective filing date of the instant application and the publication of the instant application and the technology thereof, without there being any publication of a synthesis of the compound of The Registry Handbook, the rejection is based upon impermissible hindsight gleaned from the instant invention.

Accordingly, Hirsch, either individually or in combination with Schwarz, cannot supply the deficiencies of the mere compound name in The Registry Handbook.

Therefore, The Registry Handbook (1984 Supplement) in view of Schwarz et al. (DD 114806) and Hirsch (US Patent No. 4,075,351) fails to teach or suggest 19-norpregna-1,3,5(10)-triene-20-yne-3,17-diol, 3-sulfamate as asserted in the Office Action.

Reconsideration and withdrawal of the rejection based on The Registry Handbook (1984 Supplement) in view of Schwarz et al. (DD 114806) and Hirsch (US Patent No. 4,075,351) are respectfully requested.

REQUEST FOR FURTHER INTERVIEW & CONCLUSION

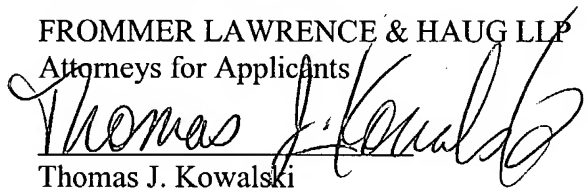
If any issue remains as an impediment to allowance, e.g., a need to supply a Terminal Disclaimer or Terminal Disclaimers in view of agreement on allowable subject matter, to obviate a double patenting rejection held in abeyance or to expedite prosecution, a further interview is

respectfully requested, with the Examiner invited to contact the undersigned telephonically to arrange a mutually convenient time and manner therefor.

In view of the amendments, remarks and attachments herewith, and the matters discussed during the interview (for which Examiner Badio and Practice Specialist Reynolds are again thanked for the courtesies extended therein), the application is in condition for allowance. Favorable reconsideration of the application, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: 

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